



BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC-2014-0005, Docket Number NIOSH-272]

Respiratory Protective Devices Used in Healthcare

Agency: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of request for information and comment.

SUMMARY: Respiratory protective devices (RPDs) that are approved by the National Institute for Occupational Safety and Health (NIOSH) and also cleared by the Food and Drug Administration (FDA)^a as medical devices are widely used in surgical and non-surgical healthcare environments. There are reports^b that other NIOSH-approved RPDs that are not FDA-cleared medical devices are also being used to protect healthcare workers from inhalation hazards. The desirability of NIOSH incorporating additional requirements and tests in its 42 CFR Part 84 respirator approval process to parallel the protections in the FDA clearance process for Surgical N95 Respirators in surgical and non-surgical

healthcare environments has been mentioned during broad-based and cross-agency discussions for future pandemic events as well as day-to-day use in healthcare settings.

NIOSH could augment the existing requirements and tests of the 42 CFR Part 84 conformity assessment process to incorporate requirements included in the FDA clearance process, such as fluid resistance and flammability. Both FDA and NIOSH require demonstration of filtration performance. The current NIOSH filtration testing requirements use non-biological aerosol based on the assumption that all particles, biological or non-biological, behave according to the same principles of aerosol physics for filtration: that is, by impaction, interception, diffusion, and electrostatic attraction. NIOSH is seeking public comment with available supporting data that either validates or disproves this assumption.

NIOSH is requesting information and comments on the following:

1. Do healthcare stakeholders anticipate expanding the use of RPDs to include elastomeric air purifying respirators and/or Powered Air Purifying Respirators (PAPRs)?
2. For protections appropriate for RPDs to be used in surgical and/or non-surgical healthcare environments, should NIOSH

consider adding tests and requirements to the 42 CFR Part 84 conformity assessment process for splash/spray protection (fluid resistance) per ASTM F1862:2000a, or other appropriate standards? NIOSH seeks evidence related to the performance of existing products (NIOSH-approved, but not FDA-cleared as a medical device) against this standard and the prevalence and characteristics of actual sprays/splashes faced by healthcare workers during non-surgical patient care.

3. For RPDs to be used in surgical and/or non-surgical healthcare environments, should NIOSH consider adding requirements and tests beyond those provided in 42 CFR Part 84 for protection against flammability hazards per 16 CFR 1610, UL 2154, or other appropriate standards? NIOSH seeks evidence related to the performance of existing products (NIOSH-approved, but not FDA-cleared as a medical device) against this standard and the prevalence and characteristics of actual flammability hazards faced by healthcare workers during patient care (i.e., non-surgical activities).

4. For RPDs to be used in surgical and/or non-surgical healthcare environments, should NIOSH consider adding

optional, supplemental filtration testing (e.g., ASTM F2101-01 (Bacterial Filtration Efficiency) and ASTM F1215:1989 (Particulate Filtration Efficiency)) in addition to the existing NIOSH filter requirements in 42 CFR Part 84? NIOSH requests evidence related to the performance of existing products (NIOSH-approved, but not FDA-cleared as a medical device) against these alternative filter test methods and the prevalence and characteristics of airborne exposures faced by healthcare workers during patient care (i.e., non-surgical activities). NIOSH seeks comparative results for testing against such candidate supplemental standards versus test results achieved in the existing filter efficiency tests of 42 CFR Part 84.

DATES: All comments must be received by [30 DAYS AFTER PUBLICATION OF THIS NOTICE]

FOR FURTHER INFORMATION CONTACT: Roland Berry Ann, NIOSH NPPTL, P.O. Box 18070, Pittsburgh, PA, 15236; (412) 386-6111 (this is not a toll-free number). Information requests can also be submitted by email to nioshdocket@cdc.gov.

ADDRESSES:

You may submit comments identified by CDC-2014-0005 and Docket Number NIOSH-272 by either of the two following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>.

Follow the instructions for submitting comments.

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MSC34, 4676 Columbia Parkway, Cincinnati, OH 45226

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2014-0005; NIOSH-272]. All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided. All electronic comments should be formatted as Microsoft Word. For access to the docket to read background documents or comments received, go to www.regulations.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under 42 CFR Part 84, NIOSH approves RPDs for protection against inhalation hazards in all occupational settings. The FDA regulates medical devices that are intended to prevent the transmission of disease in humans. FDA defines a medical device

under Section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)).

The Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogens regulation specifies masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, are to be worn whenever splashes, sprays, spatters, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. (29 CFR 1910.1030(d)(3)(x)).

The FDA clears surgical masks (e.g., laser masks or procedure masks) as medical devices^c, in that they are intended to prevent disease. They protect healthcare workers from splashes, sprays, spatters, and droplets of respiratory secretions, blood and other body fluids. The FDA may issue a premarket clearance as a medical device only for certain NIOSH-approved N95 filtering facepiece respirators (FFRs) assessed for clearance characteristics equivalent to FDA-cleared masks that are used in the healthcare setting. Currently, the only medical device classification that can be applied to a NIOSH-approved respirator is that of a Surgical N95 Respirator.

FDA regulates NIOSH-approved Surgical N95 Respirators as medical devices intended for use in healthcare settings under the regulation 21 CFR 878.4040. OSHA has the primary responsibility for enforcing proper use of RPDs in the workplace, including healthcare settings, as described in the Respiratory Protection standard (29 CFR 1910.134). According to section 1910.134, where respirators are required, they must be NIOSH-approved and used as part of a respiratory protection program which includes medical evaluation, training, and fit testing (when applicable). OSHA does not require RPDs used in a healthcare setting to be cleared by the FDA. Many RPDs used in healthcare settings have not been submitted by industry for FDA premarket clearance, and therefore have not been FDA-cleared as medical devices.

There are two general categories of RPDs found in healthcare settings: (1) Those approved by NIOSH and (2) those approved by NIOSH and receiving FDA Premarket Notification [510(k)] clearance as a Surgical N95 Respirator by the FDA. RPDs approved by NIOSH which are not cleared by FDA include NIOSH-approved N95, P95, and P100 FFRs; Powered, Air-Purifying Respirators (PAPR); and elastomeric half facepiece air-purifying respirators. The most common of these is the N95 FFR. Surgical N95 Respirators cleared by FDA and approved by NIOSH are N95

FFRs that also meet certain requirements for fluid resistance per ASTM F1862:2000a and sometimes flammability requirements per 16 CFR 1610 and UL 2154.

Applicability to Pandemic Preparedness

During the early stages of a pandemic, before vaccines are widely available and the mode(s) of disease transmission are fully understood, personal protective equipment will be an important component of a non-pharmaceutical intervention strategy to reduce disease transmission. Some of the RPDs used as part of the intervention could be RPDs in frequent or daily use for non-outbreak hazards.

Due to the expected importance of RPD use during a pandemic, the HHS recommends that healthcare facilities stockpile a 6-8 week supply of disposable N95 FFRs. However, it has been documented^d that the stockpiling recommendation has been a challenge for healthcare facilities. Noted barriers to stockpiling N95 FFRs include: lack of storage space, limited use within normal working parameters, shelf-life limitations, and working against the typical "just-in-time" supply chains, which only allow for a limited number of on-hand supplies. This is challenging due to the sheer number of RPDs that will be needed during a pandemic.

According to the CDC, an estimated 90 million N95 FFRs would be needed to protect healthcare workers during a 42-day pandemic. The rapid increase in RPD usage was apparent during the 2009 H1N1 pandemic.^{e f} RPD usage may also increase beyond pandemic recommendations due to concerns about disease transmission. Generally, N95 FFRs are the primary choice of respiratory protection over PAPRs or elastomeric respirators for numerous reasons. They are disposable and therefore do not require cleaning or reprocessing. They are lighter in weight and less cumbersome to don and doff as straps are generally not adjustable; nor are there any filter cartridges to be manipulated. Also, they are familiar to HCWs because of their resemblance to surgical masks commonly used in healthcare environments.

Because of the potential for splashes and sprays (e.g., from a severed artery, cough, or sneeze), some facilities have selected NIOSH approved and FDA-cleared Surgical N95 respirators as the primary option for protecting healthcare workers during a pandemic. However, other NIOSH-approved RPDs might need to be considered because there may not be enough of the FDA-cleared devices to protect healthcare workers and other essential personnel during a pandemic or outbreak.

NIOSH-approved respiratory protective devices that are also FDA-cleared medical devices are widely used in surgical and non-surgical healthcare environments. There are reports^{b c} that other types of NIOSH-approved RPDs that are not FDA-cleared medical devices are being used as well to protect workers in both surgical and non-surgical healthcare environments from inhalation hazards. The desirability of NIOSH incorporating additional requirements and tests in its 42 CFR Part 84 respirator approval process to parallel the protections in the FDA clearance process for Surgical N95 Respirators in surgical and non-surgical healthcare environments has been mentioned during broad-based and cross-agency planning discussions for dealing with future pandemics.

NIOSH intends to use this information to consider augmenting the existing protections of 42 CFR Part 84 to incorporate requirements included in the FDA clearance process, such as fluid resistance and flammability.^{b c} NIOSH is seeking public comment on the desirability of adding requirements and tests in its 42 CFR Part 84 respirator approval process to parallel the protections in the FDA clearance process.

Both FDA and NIOSH require demonstration of filtration performance. The current NIOSH filtration testing requirements use non-biological aerosol based on the assumption that all particles, biological or non-biological, behave according to the same principles of aerosol physics for filtration: that is, by impaction, interception, diffusion, and electrostatic attraction. NIOSH is seeking public comment with available supporting data that either validates or disproves this assumption.

Next Steps: NIOSH will determine next steps after all comments are reviewed and assessed. NIOSH intends to provide an entry to the docket regarding next steps no later than June 30, 2014.

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Date: 03/14/2014]

^a 21 CFR 878.4040 (FDA 510(K)Clearance)

^b Stradtman, L, Prevalence of Respiratory Protective Devices in U.S. Healthcare Systems, Internal NIOSH Survey Report, Jan 7, 2014. (available in docket)

^c According to the Food, Drug and Cosmetic Act, the FDA reviews for clearance medical devices that are intended to cure, mitigate, treat, or prevent disease in man.

^d (2010) NIOSH investigation of 3M model 8000 filtering facepiece respirators as requested by the California Occupational Safety and Health Administration, Division of Occupational Safety and Health, Oakland, California.

^e Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp. Infect. 2013 Nov; 85(3):165-9.

^f Association of State and Territorial Health Officials. Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic. Arlington: Association of State and Territorial Health Officials; 2010.

Dated: March 10, 2014.

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Director,

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